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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,571	04/27/2005	Jean-Marie Mathias	F2-5813	9320
44926 7590 12/12/2007 BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/501,571

Applicant(s)

MATHIAS ET AL.

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/07 has been entered.

Response to Amendment

2. In the response filed 11/9/07, applicant amended claims 1, 4, 6, and 9, and added claim 13. Claims 1-13 are currently pending.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elson et al. (US 4,643,389).

5. With respect to Claims 1, 4, 8, 9, and 13, Elson et al. (hereafter "Elson") discloses a flow control clamp comprising a flexible body made of polypropylene (as per Claim 8) having a first leg 25 and a second leg (Column 3, Lines 4-9). Because the

clamp comprises flexible hinges 29, the legs are capable of being arranged in a general facing relationship when in a first open position, and in a second closed position (see Figure 5). The clamp further comprises a pair of apertures for receiving a flexible tube therethrough, and a tube-contacting member on both legs (as per Claim 9), said contacting members holding the tube shut when the clamp is in the second position.

Elson discloses the device substantially as claimed, but does not specifically disclose that the legs are adapted to irreversibly secure the legs together in the closed position.

6. Elson further discloses a positive lock that holds the clamp shut such that it may not be opened without permanent deformation or breaking of the clamp (Column 3, Lines 61-64). Elson, therefore, suggests the need for secure and permanent attachment of a clamp to a tube element. The clamp is fully capable of irreversibly interlocking the first and second legs together, as per Claims 1 and 4. Therefore, it would have been obvious to one of ordinary skill in the art to modify the clamp of Elson with the ability to permanently lock the clamp in order to prevent the clamp from accidentally coming unattached from the tubing member during a medical procedure. Simply removing the ability of the Elson's clamp to become unlocked from the locked position does not constitute a patentable improvement in the art.

7. With respect to Claims 2 and 3, Elson discloses that the first leg comprises a pair of inwardly-projecting, spaced apart walls 43 defining a slot therebetween. The second leg includes an extension, whereby movement of the legs from the spaced apart

position to the closed position introduces the extension into the slot. With respect to Claim 3, the lip 49 comprises an inward-extending portion. See Figures 2 and 4.

8. With respect to Claim 5 one leg comprises a lip and the other leg comprises a hook 53 for engaging said lip in the closed position. See Figures 2 and 4.

9. With respect to Claim 10, the outer surface of the body is rounded, and therefore is substantially free of sharp ends and corners. See Figures 1-7.

10. With respect to Claim 11, the apertures surrounds the entire tube at the point where the tube passes through the aperture.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elson in view of Baumdicker et al. (US 6,298,526). Elson discloses the flow control clamp of Claim 1 (see rejection above), but does not disclose that the legs comprise a ball and socket closure. Baumdicker et al. disclose a tether clip comprising a first and second leg (10 and 27) that are held together by a ball 28 and socket 29. See Figures 1 and 2. Like the ball and socket in Applicant's invention, the locking system of Baumdicker et al. is shaped like a ball and socket when viewed from the axis of rotation, as shown in Figure 4. It would be obvious to one skilled in the art at the time of invention to modify the flow control clamp of Elson with the ball and socket arrangement of Baumdicker et al. in order to provide an alternate, secure method for locking a flow control clamp in the closed position.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elson in view of Stephens (US 4,193,174). Elson discloses the flow control clamp of Claims 1 and 4 (see rejection above), but does not disclose that the legs comprise a notch and peg for engaging the notch in the closed position. Stephens discloses a belt adjustment clamp comprising a first and second legs (11, 12) that are able to be locked together by a locking element that comprises peg 36 and notch 16. It would be obvious to one skilled in the art at the time of invention to modify the flow control clamp of Elson with the peg and notch configuration of Stephens in order to provide an alternate, secure method for locking a flow control clamp in the closed position.

13. Claims 1-5, 8-12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg (US 6,089,527) in view of Elson. Utterberg discloses a tubing clamp comprising a flexible body and two legs that are in a facing relationship in a first position and a second position, a pair of apertures, and a pair of tube contacting means. Both legs comprise an inward-facing extension that serves to lock the clamp in the second position. Furthermore, one leg comprises a lip and the other leg comprises a hook for engaging the lip in the closed position. The outer surface of the clamp is substantially free of sharp edges and corners. Regarding Claim 12, the leg comprising contacting member 30 appears to be substantially thinner than the leg comprising contacting member 28 (see Figures 2 and 3). This arrangement increases flexibility, thereby allowing the inward projection 22 to bend as the hook 24 engages with the lip 26. Therefore, the portion of increased flexibility serves the same purpose as that of

applicant's Claim 12. Utterberg, however, does not disclose that the first and second surfaces are adapted to irreversibly secure the legs together in the closed position.

14. Elson discloses a tubing clamp made of polypropylene for permanently sealing a flexible tube (see rejection above). It would have been obvious to one skilled in the art to combine the clamp of Utterberg with the permanent closure of Elson in order to make a tube clamp that is irreversibly closable. The use of irreversibly-closable flow control clamps is well established in the medical art, and making a closure permanent does not constitute an obvious change over the prior art. While the combination of the Utterberg and Elson references would produce a slightly different structure, it would provide a permanently closable clamp that has the same functionality as pair of inwardly projecting spaced walls of applicant's invention. Therefore, the rearrangement of parts, as discussed above, would have been an obvious variation on the prior art.

Response to Arguments

15. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Regarding applicant's argument that the clamp of Elson is not capable of irreversibly closing, any clamp is capable of being opened, even if it needs to be broken to do so. Applicant's clamp is fully capable of being opened if sufficient force is applied to it. Likewise, Elson discloses that the clamp is capable of being locked such that it may only be opened under excessive force (see column 3, lines 61-67). As discussed in the rejection above, Elson clearly anticipates the need for a clamp to be permanently

locked to a tube. Therefore, it is the examiner's position that the Elson clamp is capable of being positioned such that it is irreversibly closable, and it would have been within the scope of one of ordinary skill in the art at the time of invention to secure the clamp in the locked position such that the clamp is permanently attached to the tube.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
10/501,571
Art Unit: 3761

Page 8

PRW
12/7/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal stroke extending to the right.